UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 1:18-cv-1332

SARANAC BRAND FOODS, INC., a corporation,

HONORABLE PAUL L. MALONEY

and

DENNIS M. NOWAK and DANIEL R. NOWAK, individuals,

Defendants.

CONSENT DECREE FOR PERMANENT INJUNCTION

Plaintiff, United States of America, having filed a Complaint for Permanent Injunction against Saranac Brand Foods, Inc. ("Saranac" or "the company"), a corporation, and Dennis M. Nowak and Daniel R. Nowak, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree for Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*

3. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for

introduction, into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(k), by doing an act that causes the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of articles of food while such articles are held for sale after shipment of one or more components in interstate commerce.

5. Defendants represent that: (a) as of August 10, 2018, they have discontinued all operations related to receiving, preparing, processing, packing, holding, distributing or maintaining an inventory of any articles of food at or from their facility located at 60 South Bridge Street, Saranac, Michigan 48881 and any other locations; and (b) Saranac Brand Foods, Inc. intends to dissolve as a legal entity as soon as practicable after disposing of any remaining assets and paying off any remaining debts. If Defendants intend to resume any operations related to receiving, preparing, processing, packing, holding, or distributing any articles of food at or from 60 South Bridge Street, Saranac, Michigan 48881 or at or from any other location ("facility"), they shall notify the United States Food and Drug Administration ("FDA") at the address specified in Paragraph 21 and shall fulfill all requirements contained in Paragraph 6 prior to such resumption

6. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, franchisees, partnerships, and "doing business as" entities), who receive notice of this Decree by personal service or otherwise (collectively, "Associated Person(s)") are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the inherent equitable

authority of this Court, from directly or indirectly receiving, preparing, processing, packing, holding, and distributing articles of food, at or from their facility, unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants, the Associated Persons or their families, which is qualified to collect product and environmental samples from within Defendants' facility and analyze those samples for the presence of *Listeria*, including *Listeria monocytogenes* ("*L. monocytogenes*"), using a method that is acceptable to FDA. Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental and finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the *Listeria* Monitoring Program discussed in Paragraph 6.C. below;

B. Defendants retain, at their expense, an independent expert(s) (the "Sanitation Expert") having no personal or financial ties (other than the retention agreement) to Defendants, the Associated Persons or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants' facility and to determine whether the methods, processes, and controls are operated and administered in conformity with the Act and its implementing regulations. Defendants shall notify FDA in writing of the name(s) and qualifications of the Sanitation Expert(s) as soon as they retain such expert(s);

C. Defendants' Sanitation Expert, in consultation with the laboratory, after reviewing all FDA and Michigan Department of Agriculture & Rural Development ("MDARD")

observations from February 2012 to present, develops a written *Listeria* Monitoring Program, which shall include, at a minimum, the following:

(1) An effective written Sanitation Control Program that establishes adequate methods, processes, and controls for receiving, preparing, processing, packing, holding, and distributing articles of food to minimize the risk of introduction of pathogenic *Listeria*, any other poisonous or deleterious substances, or filth, and to ensure that Defendants' food is not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, processes, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food to prevent such articles from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") to ensure that the facility and equipment therein are continuously maintained in a sanitary condition;

(2) A written Employee Training Program that includes, at a minimum, instruction on sanitary food-handling techniques and documentation that each employee has received such training. Defendants' Sanitation Expert shall ensure that each employee fully understands the substance of the Employee Training Program;

(3) An effective program of environmental monitoring and testing of the facility to ensure that microorganisms such as *Listeria*, any poisonous or deleterious substances, and filth are not present within the facility. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, and/or distributed, and common

areas that could be reservoirs for cross-contamination), and analyzing collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) business days of receipt by Defendants; and

(4) A written plan for remedial action should pathogenic *Listeria*, any other poisonous or deleterious substance, or filth be detected;

D. Defendants assign continuing responsibility for the operation of the *Listeria* Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the facility in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

E. FDA approves, in writing, the *Listeria* Monitoring Program discussed in Paragraph 6.C. prior to its implementation;

F. The Sanitation Expert conducts a comprehensive inspection of the facility, the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary corrections and are operating in compliance with this Decree, the Act, and its implementing regulations. The Sanitation Expert shall submit all findings to Defendants and FDA concurrently, within ten (10) business days after completion of the inspection;

G. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with this Decree, the Act, and its implementing regulations, including:

(1) Documentation that Defendants have cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and documentation that Defendants have received laboratory confirmation from environmental swabbing that *Listeria* is no longer present in the facility; and

(2) Specific measures that Defendants have taken to address each of the violations documented by FDA and MDARD since February 2012;

H. Within twenty (20) business days after entry of this Decree, Defendants shall, pursuant to a written destruction plan approved in writing by FDA, destroy under FDA's supervision all raw ingredients and all in-process and finished articles of food currently in their custody, control, or possession;

I. Defendants recall, to the retail level, and destroy all finished articles of food distributed since November 29, 2017;

J. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, conducts inspections of the facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

K. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 6.A. through I. of this Decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitution for written notification; and

L. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraphs 6.A. through K., at the rates set forth in Paragraph 12 below.

7. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, franchisees, partnerships, and "doing business as" entities) who receive actual notice of this Decree are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more of their components in interstate commerce; or

C. results in the failure to implement and continuously maintain the requirements of this Decree.

8. Immediately upon resuming operations after completing the requirements of Paragraph 6 and receiving notice from FDA pursuant to Paragraph 6.K., Defendants shall, in consultation with the laboratory and the Sanitation Expert, continuously implement the following steps to prevent adulteration of food received, prepared, processed, packed, or held in, and/or distributed from, their facility:

A. Effectively implement, on an ongoing basis, the *Listeria* Monitoring Program developed pursuant to Paragraph 6.C.;

B. Conduct environmental monitoring and testing as set forth in Paragraph 6.C.(3) to ensure that the SSOPs effectively address the *Listeria* hazard and that the SSOPs are consistently followed. Environmental testing shall be performed by the laboratory in accordance with timetables and methods that Defendants submit in writing to FDA for prior written approval by FDA. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants.

C. Defendants' environmental testing shall include, at a minimum, all of the following:

(1) if a food- or non-food-contact surface tests positive for *Listeria* spp. during routine testing, intensified sampling must be initiated immediately, in conjunction with intensified sanitation measures. Intensified sampling requires that three (3) samples per day must be collected and analyzed until a total of nine (9) consecutive samples (three (3) days of intensified sampling) have tested negative for *Listeria* spp. from the site where the *Listeria* spp. was identified. After nine (9) consecutive samples have tested negative for *Listeria* spp., that site may be subject to routine sampling; and

(2) any *Listeria* spp. isolate from a food-contact surface must be tested further to determine whether it is *L. monocytogenes*. In addition, all food products that come in contact with a site that tests positive for the general strain *Listeria* spp. must be placed on hold pending laboratory test results of those food products and further testing of the *Listeria* spp. isolate from the food-contact surface. Defendants shall submit their sampling scheme for food

product testing to FDA, which sampling scheme must be acceptable to FDA. The food products can be released only if laboratory test results for the food products are negative for *L. monocytogenes* and the *Listeria* spp. isolate from the food-contact surface is not *L. monocytogenes.* If the laboratory test results for the food products and/or *Listeria* spp. isolate from the food-contact surface are positive for *L. monocytogenes*, all food products manufactured from the time the laboratory sample(s) testing positive was collected must be destroyed at Defendants' expense, under FDA's supervision, and according to a written destruction plan submitted by Defendants and approved in writing by FDA prior to implementation. Defendants shall bear the costs of FDA's supervision of such destruction at the rates specified in Paragraph 12; and

D. Conduct finished product testing in the following manner:

(1) Defendants shall test all lots of finished food products for *L. monocytogenes* for at least five (5) consecutive production days using a testing method approved in advance by FDA;

(2) After the completion of testing under Paragraph 8.D.(1), Defendants shall test at least one lot of each finished food product per day for the next twenty (20) production days;

(3) After the completion of testing under Paragraph 8.D.(2), Defendants shall test at least one lot of each finished food product every five (5) production days for the next three (3) months; and

(4) After the completion of testing under Paragraph 8.D.(3), Defendants shall test at least one lot of each finished food product monthly thereafter.

(5) If any finished food product tested pursuant to Paragraphs 8.D.(1)-(4) is positive for *L. monocytogenes*, then Defendants shall immediately cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and pursuant to a written destruction plan approved in writing by FDA, all positive food samples, as well as all food manufactured since the positive food samples were collected. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and its implementing regulations. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants.

9. If Defendants terminate or alter in any way their service contract with the laboratory retained pursuant to Paragraph 6.A., Defendants shall notify FDA within five (5) business days after such termination or alteration and immediately retain the services of another laboratory. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with a new laboratory to FDA within five (5) business days after such service contract is executed.

10. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles

of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Saranac Brand Foods, Inc. has notified the FDA that it intends to dissolve as a legal entity as soon as practicable after disposing of any remaining assets and paying off any remaining debts. Defendants shall notify FDA in writing that Saranac Brand Foods, Inc. has dissolved within fifteen (15) business days of its dissolution. Defendants shall notify FDA in writing at least fifteen (15) business days before any other change in ownership, name, or character of their business, including reorganization, relocation, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) business days before the assignment or change in business and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) business days after providing a copy of this Decree to a prospective successor or assign.

12. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of

the date that this Decree is signed by the parties, these rates are: $95.39 per hour and fraction thereof per representative for inspection or investigative work; $114.33 per hour or fraction thereof per representative for analytical or review work; $0.545 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, holding, and distributing any articles of food;

B. Require Defendants to recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with microorganisms or filth; and/or

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendant Saranac Brand Foods, Inc. shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 12.

14. Any cessation of operations as described in Paragraph 13.A. shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

15. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of two thousand dollars ($2,000.00) for each day that Defendants fail to comply with this Decree, the Act, and/or its implementing regulations; an additional sum of one thousand dollars ($1,000.00) in liquidated damages per day for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose,

additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

16. If any Defendant violates this Decree and is found in contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

17. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

18. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of this Decree to each and all of their current (as of the date of entry of the decree) officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA within twenty (20) business days after the date of entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

19. Within seven (7) days after initiating or resuming operations, Defendants shall prominently post a copy of this Decree at the facility and shall ensure that this Decree remains

posted for a period of at least six (6) months or until Defendants terminate their lease at the facility, whichever is earlier.

20. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested) to such persons. Within ten (10) business days after each instance that any Defendant becomes associated with any such additional persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all person who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Defendants shall address all communications with FDA required under this Decree to Director, Detroit District Office, Food and Drug Administration, 300 River Place Drive, Suite 5900, Detroit, Michigan 48207, and shall reference this civil action by the case name and civil action number in such communications.

22. The parties may, at any time, petition each other in writing to extend any deadline provided herein, and the parties may grant such an extension without seeking leave of the Court.

23. No sooner than five (5) years after entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this

Decree, the Act, and its implementing regulations for at least five (5) years, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

24. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 30th day of November, 2018.

/s/ Paul L. Maloney
UNITED STATES DISTRICT JUDGE

We hereby consent to entry of the foregoing Decree:

FOR DEFENDANTS:

DENNIS M. NOWAK
Individually and on behalf of
Saranac Brand Foods, Inc.

DANIEL R. NOWAK
Individually and on behalf of
Saranac Brand Foods, Inc.

MATTHEW B. EUGSTER
333 Bridge Street N.W.
P.O. Box 352
Grand Rapids, Michigan 49501-0352
616-336-6821
mbeugster@varnumlaw.com

Attorney for Defendants

FOR PLAINTIFF:

ANDREW B. BIRGE
United States Attorney
Western District of Michigan

RYAN COBB
Civil Chief
Assistant United States Attorney
330 Ionia Avenue, N.W.
Suite 501
P.O. Box 208
Grand Rapids, MI 49503
616-456-2404
Ryan.Cobb@usdoj.gov

JOSEPH H. HUNT
Assistant Attorney General
Civil Division

JAMES M. BURNHAM
Deputy Assistant Attorney General
Civil Division

GUSTAV EYLER
Acting Director
Consumer Protection Branch

CLAUDE F. SCOTT
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., 6th Fl. South
Washington, DC 20044
202-514-9471
Claude.F.Scott@usdoj.gov

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
United States Department of
Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

JOSHUA A. DAVENPORT
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002